

## Message Text

UNCLASSIFIED

PAGE 01 STATE 234433  
ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 /026 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CM

APPROVED BY OES/APT/BMP: JFRY

DHEW/PHS/OASH/OIH: RFISHCER

EUR/NE:SWORREL(INFO)

EUR/CE:SKLINGAMAN(INFO)

EUR/NE:REWOODS(INFO)

-----094411 300115Z /12

R 291222Z SEP 77

FM SECSTATE WASHDC

TO AMEMBASSY STOCKHOLM

AMEMBASSY BONN

AMEMBASSY LONDON

UNCLAS STATE 234433

E.O. 11652: N/A

TAGS: OTRA, OGEN, TBIO, ETRD, EIND, SW, GW, UK

SUBJECT: FDA REPRESENTATIVE PROVIDING TECHNICAL AND  
CONSULTATIVE ASSISTANCE TO FOREIGN DEVICE MANUFACTURERS

1. FDA ADVISES THAT DAVID MAKANANI, ENGINEER, DALLAS  
DISTRICT OFFICE WILL BE IN EUROPE OCTOBER 15-NOVEMBER 14,  
1977.

2. MR. MAKANANI WILL VISIT 4 DEVICE MANUFACTURERS TO  
DETERMINE IF THEIR FACILITIES AND OPERATIONS ARE IN ACCORD-  
ANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS  
AND WILL REPORT ANY SIGNIFICANT DEVIATIONS THAT WILL AFFECT  
THE SAFETY AND/OR EFFICACY OF SUCH DEVICES WHICH THEY MAY  
IMPORT INTO THE UNITED STATES.

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3. ITINERARY AS FOLLOWS:

OCTOBER 14, 1977 - DEPART WASHINGTON, D.C. FOR STOCKHOLM,  
SWEDEN

OCTOBER 17-21 - VISIT JUNGER

OCTOBER 22 - TRAVEL STOCKHOLM, SWEDEN TO FRANKFURT  
- GERMANY

OCTOBER 24-28 - VISIT RUSCH

OCTOBER 29 - TRAVEL FRANKFURT TO ERLANGEN

OCTOBER 31 - NOVEMBER 4 - VISIT SIMENS

NOVEMBER 5 - TRAVEL ERLANGEN, GERMANY TO  
LONDON, ENGLAND

NOVEMBER 7-11 - VISIT BRITISH OXYGEN CORPORA-  
TION

NOVEMBER 14 - TRAVEL LONDON, ENGLAND TO WASH-  
INGTON, D.C.

4. ASSISTANCE OF EMBASSIES WILL NOT BE REQUIRED. CHRISTOPHER

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NNN

## Message Attributes

**Automatic Decaptoning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** TECHNICAL ASSISTANCE, MANUFACTURES, INSPECTIONS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 29-Sep-1977 12:00:00 am  
**Decapton Date:** 01-Jan-1960 12:00:00 am  
**Decapton Note:**  
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**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE234433  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:CM  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770356-0074  
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**Litigation Codes:**  
**Litigation History:**  
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**Message ID:** 46d37f47-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
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**Review Release Event:** n/a  
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**Review Withdrawn Fields:** n/a  
**SAS ID:** 1292812  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA REPRESENTATIVE PROVIDING TECHNICAL AND CONSULTATIVE ASSISTANCE TO FOREIGN DEVICE MANUFACTURERS  
**TAGS:** OTRA, OGEN, TBIO, ETRD, EIND, SW, GE, UK  
**To:** STOCKHOLM BONN MULTIPLE  
**Type:** TE  
**vdkvgwkey:** odbc://SAS/SAS.dbo.SAS\_Docs/46d37f47-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009